

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: **Garvey et al**

Application No.: **10/694,183**

Filed: **October 28, 2003**

For: **Phosphodiesterase Inhibitors and Nitric Oxide Donors,  
Compositions and Methods of Use**

Docket No: 102258.287US4

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450



**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants bring to the attention of the Examiner the documents listed on the attached PTO-1449 Form.

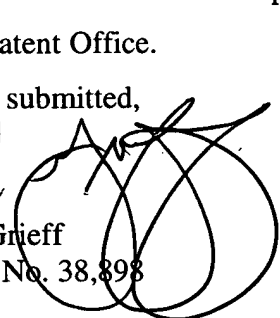
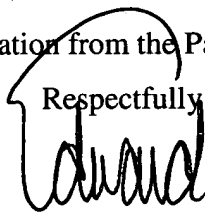
A copy of each of the cited references is being submitted herewith. A copy of the cited U.S. patents and U.S. publications are not being submitted pursuant to 37 CFR § 1098(e).

The submission of this Information Disclosure Statement does not represent that a search has been made and does not constitute an admission that the listed documents are material to patentability or that the listed documents are prior art.

This Information Disclosure Statement is being submitted before the mailing date of a first office action on the merits or a notice of allowance. Accordingly, no fee is due.

Applicants respectfully request that the Examiner initial and return a copy of the enclosed PTO-1449 Form with the next communication from the Patent Office.

Respectfully submitted,



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Date: December 15, 2003  
HALE AND DORR LLP  
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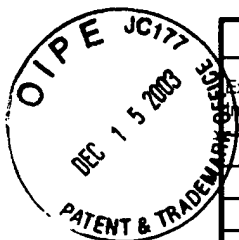
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Substitute for form 1449A/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Application Number		
			Filing Date		
			First Named Inventor		
			Group Art Unit		
			Examiner Name		
Sheet	1	of	6	Attorney Docket Number	102258.287 US4



U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		6,476,037	B1	Wallace	11-05-2002	
		6,133,272		Garvey et al	10-17-2000	
		6,172,060		Garvey et al	01-09-2001	
		6,172,068		Garvey et al	01-09-2001	
		6,177,428		Garvey et al	01-23-2001	
		6,197,782		Garvey et al	03-06-2001	
		6,197,778		Garvey et al	03-06-2001	
		6,211,179		Garvey et al	04-03-2001	
		6,211,881		Garvey et al	04-24-2001	
		6,232,321		Garvey et al	05-15-2001	
		6,316,457		Garvey et al	11-13-2001	
		6,462,044		Garvey et al	10-08-2002	
		6,331,543		Garvey et al	12-18-2001	
		5,958,926		Garvey et al	09-28-1999	
		RE37,234		Garvey et al	06-19-2001	
		5,874,437		Garvey et al	02-23-1999	
		5,767,160		Kaesemeyer	06-16-1998	
		5,891,459		Cooke et al	04-06-1999	
		5,919,474		Place et al	07-06-1999	
		6,071,272		Hoffman et al	06-06-2000	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	/	WO	98/19672		NitroMed, Inc.	05-14-1998		
	/	WO	98/58633		Queen's University	12-30-1998		
	/	WO	99/51252 		Daily Wellness Co	10-14-1999		
	/	WO	00/00212		Nutracorp Sci.	01-06-2000		
	/	WO	00/15233		Zonaqen, Inc.	03-23-2000		

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Sheet

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### OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Wallace et al, Anesth. Analg., 90:840-846 (2000).	
		Clarkson et al, J. Clin. Invest., 97(8):1989-1994 (1996).	
		Creager et al, J. Clin. Invest., 90:1248-1253 (1992).	
		Doherty, "Oral, Transdermal, and Transurethral Therapies for Erectile Dysfunction," Male Infertility and Dysfunction, Chapter 33, pages 452-467 Hellstrom, Ed., Springer Verlag, New York, NY	
		Egashira et al, Circulation, 94(2):130-134 (1996).	
		Golino et al, N. Engl. J. Med., 324(10):641-648 (1991).	
		Hasdai et al, Circulation, 96(10):3390-3395 (1997).	
		Moncada et al, Biochem. Soc. Trans., 17:642-644 (1989).	
		Moncada et al, Biochemical Pharmacology, 38(11):1709-1715 (1989).	
		Nakanishi et al, Am. J. Physiol., 263 (6 Pt. 2):H1650-H1658 (1992).	
		Palmer et al, Biochem. Biophys. Res. Commun., 153:1251-1256 (1988).	

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		Richard et al, Am. J. Physiol., 259:H1433-H1439 (1990).	
		Ueno et al, J. Cardiovascular Pharmacology, 26(Supp. 4):S13-S20 (1995).	
		Vallance et al, Lancet, 2:997-1000 (1989).	
		Wallace et al, Anesthesiology, 90:1577-1586 (1999).	
		Ballard, J. Urology, 159(6):2164-2171 (1998).	
		Bellamy et al, Cardiovasc. Res., 40(2):410-417 (1998).	
		Bossaller, Basic Res. Cardiol., 82(4):396-404 (1987).	
		Ceremuzynski et al, Am. J. Cardiol., 80(3):331-333 (1997).	
		Chester et al, Lancet, 336(8720):897-900 (1990).	
		Drexler et al, Lancet, 338:1546-1550 (1991).	
		Furchgott et al, Blood Vessels, 24(3):145-149 (1987).	

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		Hiramatsu et al, Ann. Thorac. Surg., 60(5):1187-1192 (1995).	
		Jackson et al, Am. J. Cardiol., 83(5A):13C-20C (1999).	
		Klein et al, Eur. Heart J., 16(5):603-609 (1995).	
		Kobayashi et al, Coron. Artery Dis., 10(5):321-326 (1999).	
		Koifman et al, J. Am. Coll. Cardiol., 26(5):1251-1256 (1995).	
		Pearson, Ann. Thorac. Surg., 51(5):788-793 (1991).	
		Polson, Annual Review Pharmacol., 26(Suppl. 4):S13-S20 (1996).	
		Simonetti et al, "Biphasic effect of nitroglycerin on coronary hemodynamics in normal subjects," Z. Kardiol., 78(Suppl. 2):52-55; discussion 64-67 (1989).	
		Vallance et al, Cardiovasc. Res., 23:1053-1057 (1989).	
		Vallance et al, Biomed. Pharmacother., 43:113-119 (1989).	
		Webb et al, Am. J. Cardiol., 83(5A):21C-28C (1999).	

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